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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/778,002	02/11/2004	Birgit Oppmann	DX0935KB	3603
28008	7590	09/12/2007		
DNAX RESEARCH INC. LEGAL DEPARTMENT 901 CALIFORNIA AVENUE PALO ALTO, CA 94304			EXAMINER HAYES, ROBERT CLINTON	
			ART UNIT	PAPER NUMBER
			1649	
			MAIL DATE	DELIVERY MODE
			09/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/778,002	Applicant(s) OPPMANN ET AL.	
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 41-45 and 48-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-45 and 48-56 is/are allowed.
- 6) ☒ Claim(s) 57-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 7/2/07 has been entered.
2. The rejection of claims 46-48 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn due to the cancellation or amendment of the claims.
3. The rejection of claims 31-40 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to the cancellation of the claims.
4. Applicant's arguments filed 7/2/07 has been fully considered but they are not deemed to be persuasive.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 41-45 & 48-56 are allowed.
7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 57-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for compositions comprising the human IL-B60/ human CLF-1 polypeptide complex consisting SEQ ID NOs: 2 & 12, respectively, does not reasonably provide enablement for any random fragments of putative cytokine complexes with little recited structural and functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for similar reasons made of record for cancelled claims 31-40 in Paper No: 20070327, and as follows.

As previously made of record, page 64 of the specification merely invites others to “determine the critical residues in IL-B60 - IL-B60 receptor interactions”. And that “[h]elices A and D [of IL-B60 of SEQ ID NO: 2] are most important in [this] receptor interaction, with the D helix the more important region [which is not the same as the IL-B60-CLF-1 complex binding to a receptor complex comprising CNTF-R, gp130 and LIF-R, as claimed, and versus only the “helix A, helix B, helix C, *or* helix D” of SEQ ID NO: 2 being claimed to form each component of the claimed soluble cytokine complex]. In other words, the specification fails to provide any disclosure on what critical amino acids would structurally constitute a functional fragment of a soluble cytokine complex that binds to a receptor complex comprising CNTF-R, gp130 and LIF-R, as claimed. Additionally, it is unknown and not disclosed what constitutes a functional “fragment of... a mature form of SEQ ID NO: 12” (i.e., a functional fragment of the CLF-1 component of the claimed soluble cytokine complex), thereby, preventing one skilled in the art from knowing how to make and use such, because the specification provides no guidance on what critical amino acid residues structurally constitute a functional fragment of any CLF-1

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polypeptide. Therefore, any such broadly claimed polypeptides without sufficient definable structural and functional characteristics would be expected by the skilled artisan to encode inactive proteins; consistent with the teachings of Rudinger previously made of record without requiring undue experimentation to determine otherwise.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

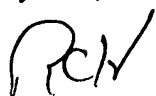
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (571) 272-0841. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.  
September 10, 2007

ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER